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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,772	02/25/2002	Peter Droge	DEBE:008US	4391

7590 07/29/2003

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

13

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/082,772

Applicant(s)

DROGE ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 29-60 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Claims 29-60 are pending in the present application, and they are subjected to the following restrictions.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 29-51 and 58, drawn to a method of sequence specific recombination of DNA in a eukaryotic cell, wherein the method is performed *in vitro* (e.g., a cell culture), and an isolated eukaryotic cell obtainable from the same method, classified in class 435, subclass 462.
- II. Claims 29-53 and 58, drawn to a method of sequence specific recombination of DNA in a eukaryotic cell, wherein the method is performed in a vertebrate organism, and a eukaryotic cell obtainable from the same method, classified in class 514, subclass 44.
- III. Claims 54-57, drawn to a nucleic acid comprising the sequence of SEQ ID NO:5, or a derivative thereof having as many as six substitutions, with the provision that the derivative is not the wild-type attP sequence, and a vector comprising the same, classified in class 536, subclass 23.1; class 435, subclass 320.1.
- IV. Claims 59-60, drawn to a non-human transgenic organism comprising at least one cell made according to the DNA recombination method of the

present invention, wherein said organism is a mouse, classified in class 800, subclass 13.

V. Claims 59-60, drawn to a non-human transgenic organism comprising at least one cell made according to the DNA recombination method of the present invention, wherein said organism is a rat, classified in class 800, subclass 14.

VI. Claims 59-60, drawn to a non-human transgenic organism comprising at least one cell made according to the DNA recombination method of the present invention, wherein said organism is a rabbit, classified in class 800, subclass 14.

VII. Claims 59-60, drawn to a non-human transgenic organism comprising at least one cell made according to the DNA recombination method of the present invention, wherein said organism is a hamster, classified in class 800, subclass 14.

Claims 29-51 link patentably distinct inventions of Groups I and II that lack the unity of invention. This is because the method of sequence specific recombination of DNA in a eukaryotic cell *in vitro* of Group I and the method of sequence specific recombination of DNA in a eukaryotic cell in a vertebrate organism of Group II are distinct methods having different starting materials, different method steps and different technical considerations for achieving different desired end-results contemplated by Applicants (e.g., contemplated therapeutic results for the *in vivo* method of Group II, see page 17 lines 12-14 of the present application). As set forth in MPEP 803.02, unity of

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invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Similarly, claim 59 link patentably distinct inventions of Groups IV-VII that lack the unity of invention. This is because a transgenic mouse, a transgenic rat, a transgenic rabbit, a transgenic hamster of Groups IV-VII, respectively, are distinct transgenic non-human organisms having no substantial common structural features or phenotypes. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

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The methods of Groups I-II are distinct one from the others as they are drawn to methods having different starting materials, different method steps and therefore they require different technical considerations for achieving different desired end-results as already discussed above.

The nucleic acid of Group III is not required for the practice of any of the methods in Groups I and II. Additionally, the nucleic acid of Group III is chemically and physically distinct from any of the non-human transgenic organisms of Groups IV-VII.


The non-human transgenic organisms of Groups IV to VII are chemically and structurally distinct one from the others for the reasons already discussed above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements (e.g., different classification as well as different literature searches), it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.

  
PATENT EXAMINER  
A.U. 1636